

1 What is claimed is:

2
3 1. A stented graft that can alternately include a compact configuration having a
4 first diameter and an expanded configuration having a greater diameter,
5 comprising, in combination:

6 ☐ at least one stent formed in a generally cylindrical shape having an
7 outer surface and a hollow bore extending longitudinally therethrough,
8 wherein said stent can alternately exist in a compact configuration
9 having a first diameter, and an expanded configuration having a
10 greater diameter and a plurality of lateral openings; and,

11 ☐ a flexible, porous, biocompatible tubular elastomer covering having a
12 first end, a second end, an outer surface and a hollow bore that
13 extends longitudinally therethrough to define an inner surface;

14 said stent being deployed coaxially within said hollow bore of said covering
15 such that said inner surface of said tubular covering is in contact with said outer
16 surface of said stent.

17
18 2. The stented graft of claim 1 wherein said stent is
19 formed of a multiplicity of wire members that are braided into said generally
20 cylindrical shape, and wherein said lateral openings in said stent are formed
21 by gaps between adjacent wire members.

22
23 3. The stented graft according to claim 1, wherein said stent and said covering
24 are anchored to each other by means for anchoring.

- 1
- 2 4. The stented graft according to claim 2, wherein said stent and said covering
- 3 are anchored to each other by at least one end of at least one said wire
- 4 members that is fixidly embedded in said covering.
- 5
- 6 5. The tubular stented graft according to claim 3, wherein said tubular elastomer
- 7 covering is anchored to said stent by means for anchoring comprising
- 8 protrusions of said covering that fixidly protrude into said lateral openings in
- 9 said stent.
- 10
- 11
- 12 6. The stented graft of claim 1 wherein said elastomer covering is formed of an
- 13 elastomer selected from the group consisting of polytetrafluoroethylene,
- 14 fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl
- 15 ether copolymer, polyvinyl chloride, polypropylene, polyethylene
- 16 terephthalate, broad fluoride; and, other biocompatible plastics.
- 17
- 18
- 19 7. The stented graft of claim 1 wherein said elastomer covering is formed of
- 20 expanded, sintered PTFE tape, said tape having been wound about the outer
- 21 surface of said stent to create said covering thereon.
- 22
- 23 8. The stented graft of claim 6, wherein said polytetrafluoroethylene is expanded
- 24 polytetrafluoroethylene having fibrils.
- 25

1 9. The stented graft of claim 8, wherein said fibrils measure up to about 300 μ in
2 length.

3
4 10. The stented graft of claim 8, wherein said fibrils measure up to about 200 μ in
5 length.

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7 11. The stented graft of claim 8, wherein said fibrils measure up to about 100 μ in
8 length.

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10 12. The stented graft of claim 8, wherein said fibrils measure up to about 50 μ in
11 length.

12
13 13. The stented graft of claim 8, wherein said fibrils measure up to about 5 μ in
14 length.

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16 14. The stented graft of claim 7 wherein said tape has a width of less than about
17 1 inch.

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19 15. The stented graft of claim 7 wherein said tape has a thickness of less than
20 0.015 inch and wherein said tape is wound about said stent in overlapping
21 fashion, such that said elastomer covering comprises 1 to 10 layers of said
22 tape.

23

1 16. The stented graft of claim 7 wherein said tape is helically wrapped
2 about said stent.

3
4 17. The stented graft of claim 7 wherein said tape has a width of 0.5
5 inches (1.27 cm), and wherein said tape is helically wrapped such that 6-8
6 revolutions of tape are applied per longitudinal inch (2.54 cm.) of said stented
7 graft.

8
9 18. The stented graft of claim 16 wherein said tape is helically wrapped
10 alternately in a first direction and then in the opposite direction.

11
12 19. The stented graft of claim 18 further comprising 8 layers of said tape.

13
14 20. The stented graft of claim 1 wherein said stent is a self-expanding
15 stent.

16
17 21. The stented graft of claim 20, wherein said self-expanding stent
18 comprises a shape memory alloy which can alternately exist in a first and a
19 second crystalline state, wherein said stent assumes a radially
20 expanded configuration when said shape memory alloy is in said first
21 crystalline state, and a radially compact configuration
22 when said shape memory alloy is in said second crystalline state.
23

1 22. The stented graft of claim 1 wherein said stent is a pressure-
2 expandable stent.

3
4 23. The stented graft of claim 22 wherein said stent is formed of
5 a metal alloy wherein the alloying residue is iron and wherein the iron is
6 alloyed with at least one other element selected from the group consisting
7 of cobalt, chromium, nickel, and molybdenum.

8
9 24. The stented graft of claim 21 wherein said shape memory alloy comprises at
10 least about 51% to about 59% nickel and the remainder comprising titanium.

11
12 25. The stented graft of claim 21 wherein said shape memory alloy comprises
13 about 0.25% chromium, at least about 51% to about 59% nickel, and the
14 remainder comprising titanium.

15
16 26. The stented graft of claim 2 wherein some of said wire members of
17 said stent are helically wound about a longitudinal axis in a first
18 direction, and others of said wire members are helically wound about said
19 longitudinal axis in a second direction such that they cross on opposite
20 sides of the wire members which had been wound in the first helical
21 direction, thereby forming a helically braided, cylindrical, wire stent.

22
23 27. The stented graft of claim 1 wherein said stent is formed of a

1 multiplicity of plastic members which are braided into said generally
2 cylindrical shape, and wherein said lateral openings in the stent are
3 formed by gaps which exist between adjacent plastic members.
4

5 28. The stented graft of claim 27 wherein said plastic members are formed
6 of a plastic selected from the group consisting of polytetrafluoroethylene,
7 fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl
8 ether copolymer, polyvinyl chloride, polypropylene, polyethylene
9 terephthalate, broad fluoride, and, other biocompatible plastics.

10
11 29. The stented graft of claim 1 wherein said covering has a
12 thickness of less than 0.1 inch (0.25 cm.)
13

14 30. The stented graft of claim 7 wherein said PTFE tape has a thickness
15 of less than 0.015 inches (0.038 cm.), said tape being wrapped about said
16 stent in overlapping fashion so as to form said covering.
17

18 31. The stented graft of claim 7 wherein said PTFE tape has a density of
19 less than 1.6 g/cc.
20

21 32. The stented graft of claim 7 wherein said covering has a thickness of less
22 than 0.1 inch (0.25 cm.) and the PTFE tape has a density of less than 1.6
23 g/cc.

1
2 33. The stented graft of claim 1 wherein said stent further comprises a polymer
3 coating formed on said stent.

4
5 34. The stented graft of claim 33 wherein the polymer coating formed on
6 said stent is of a polymer material selected from the group consisting of
7 polytetrafluoroethylene, fluorinated ethylene propylene,
8 polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl
9 chloride, polypropylene, polyethylene terephthalate, polyvinylidene fluoride,
10 and, other biocompatible plastics.

11
12 35. The stented graft of claim 33 wherein said polymer coating was
13 applied to said stent by the steps of:
14 ☐ immersing said stent in a liquid polymer dispersion;
15 ☐ removing said stent from said liquid polymer dispersion; and,
16 ☐ drying said liquid polymer dispersion that has remained on said stent,
17 whereby said polymer coating is formed on said stent.

18
19 36. The stented graft of claim 33 wherein said polymer coating is formed
20 by electron beam deposition.

21
22 37. The stented graft of claim 33 wherein said stent comprises a
23 plurality of elongate members, and wherein said polymer coating is formed

on said elongate members by positioning a polymer tube around each elongate member.

38. The stented graft of claim 33 wherein said tubular covering is adherent to said polymer coating.

39. A method for the treatment of cardiovascular disease, comprising implanting the stented graft of claim 1 in a patient in need of such treatment wherein said implantation is effective to ameliorate one or more of the symptoms of said cardiovascular disease.

40. An article of manufacture, comprising packaging material and the stented graft of claim 1 contained within the packaging material, wherein said stented graft is effective for implantation in a patient afflicted with cardiovascular disease, and the packaging material includes a label that indicates that said device is effective for said implantation.

41. A stented graft that can alternately include a compact configuration having a first diameter and an expanded configuration having a greater diameter, comprising, in combination:

- at least one stent formed in a generally cylindrical shape having an outer surface and a hollow bore extending longitudinally therethrough to form an inner surface, wherein said stent can alternately exist in a compact configuration having a first diameter, and an expanded

configuration having a greater diameter and a plurality of lateral openings; and,

- a tubular inner graft formed of an elastomer, said tubular inner graft having an outer surface and an inner surface, said tubular inner graft being deployed coaxially within said hollow bore of said stent; whereby said outer surface of said tubular inner graft is in contact with said inner surface of said stent.

42. The stented graft of claim 41 wherein said stent is formed of a multiplicity of wire members that are braided into said generally cylindrical shape, and wherein said lateral openings in said stent are formed by gaps between adjacent wire members.

43. The stented graft according to claim 41, wherein said stent and said tubular inner graft are anchored to each other by means for anchoring.

44. The stented graft according to claim 42, wherein said stent and said tubular inner graft are anchored to each other by at least one end of at least one said wire members that is fixidly embedded in said tubular inner graft.

45. The stented graft according to claim 42, wherein a plurality of lateral openings exist in said stent when said stent is at its radially expanded second diameter; and, said tubular inner graft is anchored to said stent by means for anchoring

1 comprising protrusions of said tubular inner graft that fixidly protrude into said
2 lateral openings in said stent.

3
4 46. The stented graft of claim 41 wherein said elastomer is selected from the
5 group consisting of polytetrafluoroethylene, fluorinated ethylene propylene,
6 polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer, polyvinyl
7 chloride, polypropylene, polyethylene terephthalate, broad fluoride; and, other
8 biocompatible plastics.

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10 47. The stented graft of claim 41 wherein said tubular inner graft is formed
11 of PTFE.

12
13 48. The stented graft of claim 47, wherein said PTFE is expanded
14 polytetrafluoroethylene having fibrils.

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16 49. The stented graft of claim 48, wherein said fibrils measure up to about 300 μ
17 in length.

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19 50. The stented graft of claim 48, wherein said fibrils measure up to about 200 μ
20 in length.

21
22 51. The stented graft of claim 48, wherein said fibrils measure up to about 100 μ
23 in length.

1 52. The stented graft of claim 48, wherein said fibrils measure up to about 50 μ in
2 length.

3
4 53. The stented graft of claim 48, wherein said fibrils measure up to about 5 μ in
5 length.

6
7 54. The stented graft of claim 41 wherein said stent is a self-expanding
8 stent.

9
10 55. The stented graft of claim 54, wherein said self-expanding stent
11 comprises a shape memory alloy that can alternately exist in a first and a
12 second crystalline state, wherein said stent assumes a radially expanded
13 configuration when said shape memory alloy is in said first crystalline state, and
14 a radially compact configuration when said shape memory alloy is in said second
15 crystalline state.

16
17 56. The stented graft of claim 41 wherein said stent is a pressure-
18 expandable stent.

19
20 57. The stented graft of claim 56 wherein said stent is formed of
21 a metal alloy wherein the alloying residue is iron and wherein the iron is
22 alloyed with at least one other element selected from the group consisting
23 of cobalt, chromium, nickel, and molybdenum.

1
2 58. The stented graft of claim 55 wherein said stent is formed of
3 a shape memory alloy comprising at least about 51% to about 59% nickel
4 and the remainder comprising titanium.
5

6 59. The stented graft of claim 54 wherein said stent is formed of
7 a shape memory alloy comprising about 0.25% chromium, at least about
8 51% to about 59% nickel, and the remainder comprising titanium.
9

10 60. The stented graft of claim 42 wherein some of said wire members of
11 said stent are helically wound about a longitudinal axis in a first
12 direction, and others of said wire members are helically wound about said
13 longitudinal axis in a second direction such that they cross on opposite
14 sides of the wire members which had been wound in the first helical
15 direction, thereby forming a helically braided, cylindrical, wire stent.
16

17 61. The stented graft of claim 41 wherein said stent is formed of a
18 multiplicity of plastic members which are braided into said generally
19 cylindrical shape, and wherein said lateral openings in the stent are
20 formed by gaps which exist between adjacent plastic members.
21

22 62. The stented graft of claim 61 wherein said plastic members are formed
23 of a plastic selected from the group consisting of polytetrafluoroethylene,

1 fluorinated ethylene propylene, polytetrafluoroethylene-perfluoroalkyl vinyl
2 ether copolymer, polyvinyl chloride, polypropylene, polyethylene
3 terephthalate, broad fluoride, and, other biocompatible plastics.

4
5 63. The stented graft of claim 41 further comprising a polymer coating formed on
6 said stent.

7
8 64. The stented graft of claim 63 wherein said polymer coating is selected from
9 the group consisting of polytetrafluoroethylene, fluorinated ethylene
10 propylene, polytetrafluoroethylene-perfluoroalkyl vinyl ether copolymer,
11 polyvinyl chloride, polypropylene, polyethylene terephthalate, polyvinylidene
12 fluoride; and, other biocompatible plastics.

13
14 65. The stented graft of claim 63 produced by the steps of:

- 15 ☐ immersing said stent in a liquid polymer dispersion;
- 16 ☐ removing said stent from said liquid polymer dispersion; and,
- 17 ☐ drying said liquid polymer dispersion that has remained on said stent,
- 18 whereby said polymer coating is formed on said stent.

19
20 66. The stented graft of claim 63 wherein said polymer coating was formed
21 on the stent by electron beam deposition.

22
23 67. The stented graft of claim 63 wherein said stent is formed of a

1 plurality of elongate members, and wherein said polymer coating was formed
2 on said elongate members by positioning a polymer tube around each
3 elongate member.

4
5 68. The stented graft of claim 63 wherein said tubular inner graft is adherent to
6 said polymer coating on said stent.

7
8 69. A method for the treatment of cardiovascular disease, comprising
9 implanting the stented graft of claim 41 in a patient in need of such treatment
10 wherein said implantation is effective to ameliorate one or more of the
11 symptoms of said cardiovascular disease.

12
13 70. An article of manufacture, comprising packaging material and the stented
14 graft of claim 41 contained within the packaging material, wherein said
15 stented graft is effective for implantation in a patient afflicted with congestive
16 heart failure, and the packaging material includes a label that indicates that
17 said stented graft is effective for said implantation.

18
19 71. An improved stented graft which is alternately deployable in a radially
20 compact configuration having a first diameter and a radially expanded

1 configuration having a second diameter, said stented graft comprising:

2 • a stent comprising:

- 3 □ at least one member formed in a generally cylindrical shape having
4 an outer surface and a hollow bore which extends longitudinally
5 therethrough to define an inner surface;
6 □ said stent being initially radially collapsible to a diameter which
7 is substantially equal to said first diameter of the stented graft, and
8 subsequently radially expandable to a diameter which is
9 substantially equal to said second diameter of the stented graft;
10 and,
11 □ a plurality of lateral openings existing in said stent when said stent is
12 at its radially expanded second diameter;

13 • a continuous, tubular PTFE covering formed on said stent, said PTFE
14 covering comprising:

- 15 □ a tubular inner base graft formed of expanded, sintered PTFE, said
16 tubular base graft having an outer surface and an inner surface, said
17 tubular base graft being deployed coaxially within the hollow bore of
18 said stent such that the outer surface of the tubular base graft is in
19 contact with the inner surface of the stent, and the inner surface of
20 said tubular base graft thereby defining a luminal passageway through
21 the stented graft; and,
22 □ a tubular outer layer formed of expanded, sintered PTFE tape which
23 has a width of less than about 1 inch, said tape having been wound
24 about the outer surface of said stent to create said tubular outer layer

1 thereon, such that said stent is captured between said outer layer and
2 said tubular base graft;
3 said tubular outer layer being attached to said tubular base graft,
4 through said lateral openings in said stent, to thereby form an integrally
5 stented, continuous PTFE tube which is alternately disposable in said
6 radially compact configuration of said first diameter and said radially
7 expanded configuration of said second diameter, wherein the improvement
8 comprises expanded, sintered PTFE having fibrils.
9

10 72. The stented graft of claim 71, having said fibrils up to about 300 μ in length.

11
12 73. The stented graft of claim 71, having said fibrils up to about 200 μ in length.

13
14 74. The stented graft of claim 71, having said fibrils up to about 100 μ in length.

15
16 75. The stented graft of claim 71, having said fibrils up to about 50 μ in length.

17
18 76. The stented graft of claim 71, having said fibrils up to about 5 μ in length.

19
20 77. The stented graft of claim 71 wherein said stent is formed of

21 a shape memory alloy comprising at least about 51% to about 59% nickel and
22 the remainder comprising titanium.
23

24 78. The stented graft of claim 71 wherein said stent is formed of

25 a shape memory alloy comprising about 0.25% chromium, at least about 51%

1 to about 59% nickel, and the remainder comprising titanium.

2

3 79.A method for the treatment of cardiovascular disease, comprising

4 implanting the stented graft of claim 71 in a patient in need of such treatment

5 wherein said implantation is effective to ameliorate one or more of the

6 symptoms of said cardiovascular disease.

7

8 80.An article of manufacture, comprising packaging material and the stented

9 graft of claim 71 contained within the packaging material, wherein said

10 stented graft is effective for implantation in a patient afflicted with

11 cardiovascular disease, and the packaging material includes a label that

12 indicates that said stented graft is effective for said implantation.

13